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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,157	10/13/2006	Michael Paul Brown	19610	7808

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EXAMINER
HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
05/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,157	BROWN ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on *01/20/2010* in response to office action mailed on 07/20/2009 has been acknowledged.

Claims 1-19 and 21 are pending and presently under examination.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

Applicants arguments in the response filed on *01/20/2010* are fully considered while writing this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-19 and 21 stand rejected under 102(b) as being anticipated by Hwang et al., (1999, Current Opinion in Molecular Therapeutics 1:471-479; art of record).

The above claims are drawn to a genetic vaccine construct comprising an avipox virus vector that encodes and expresses in a subject a xenogenic prostate specific polypeptide or a derivative thereof, without productively infecting said subject and further drawn to a said genetic vaccine construct additionally comprising a sequence of nucleotides encoding an immunostimulatory polypeptide and still further drawn a hybridization probe for detecting said constructs.

Regarding the claims Hwang teaches vaccine construct comprising an avipox virus (Fowlpox virus) vector and encoding and expressing a prostrate specific polypetide (see entire article; abstract; p.473, col.1-2 bridging p.474; Table 1). Hwang further teaches that

the fowlpox virus vector does not exhibit pathogenic replication indicating it does not productively infect the targeted mammalian subject (human, rodent etc.; see p.473; col.1, Table 2). Hwang further teaches advantages of using a xenogenic form of a prostate specific polypeptide in generating antigen specific CTL and antibodies using xenogenic PAP in a case study with rats where it stimulates autoimmune prostatitis (p.472, col.1; (p.474, col.1). Hwang still further teaches genetic vaccine constructs additionally using co-expression of immunomodulating (immunostimulatory) protein such as IL-2 with the target prostrate tumor specific antigen improved the immunotherapeutic effect of poxvirus (p.475. co.2, paragraphs 3-6 bridging p.476). Hwang still further teaches identification and molecular cloning of various prostrate-cancer associated antigens including prostatic acid phosphatase (PAP, PSA etc) that can be targeted as vaccine. Regarding claim 21, it is inherent that the probe can be generated from the nucleic acid sequences of said vaccine construct. Thus the cited reference clearly teaches the invention as instantly claimed.

Response to Applicants' Arguments of *01/20/2010:*

The Applicant argues that Hwang reference only discusses the proposed immunotherapeutic strategies using recombinant pox viruses but does not demonstrate the invention as such.

Applicants, arguments are however, found not persuasive because Hwang clearly teaches all the claimed limitations of the instant invention and hence still remains valid 102(b) reference and hence the rejection is maintained. Applicants' argument that Hwang does not teach co-expression of immuno-modulatory cytokine is incorrect. Hwang clearly teaches co-expression of immune modulators with tumor antigen can improve immunotherapeutic effect of pox viruses (including canary pox, fowl pox viruses) (see p.476, co.1, 2nd paragraph). Further Hwang also teaches advantages of using a xenogenic form of a prostate specific polypeptide in generating antigen specific CTL and antibodies using xenogenic PAP in a case study with rats where it stimulates autoimmune prostatitis (p.472, col.1; 3rd paragraph; p.474, col.1).

Claims 1, 3-6, 11-17, 19 and 21 stand rejected under 102(e) as being anticipated by McNeel et al., (US2004/01428290 A1; art of record).

The above claims are drawn to a genetic vaccine construct comprising an avipox virus vector that encodes and expresses in a subject a xenogenic prostate specific polypeptide or a derivative thereof, without productively infecting said subject and further and further drawn to a hybridization probe for detecting said constructs.

Regarding the claims McNeel teaches vaccine construct comprising a poxvirus vector (vaccinia vrus) and encoding and expressing a xenogenic prostrate specific polypeptide, specifically prostatic acid phosphatase (human), and administering to a rat (see entire article; abstract; p.10 col.2 paragraphs 0087-0091). McNeel further teaches using fowlpox virus vector expressing the same antigenic polypeptide (PAP) as a "boost" in the prime boost protocols (p.6, paragraph 0046). Fowl poxvirus is amply known in the prior art (inherent in the prior art) for not exhibiting pathogenic replication indicating it does not productively infect the targeted mammalian subject. McNeel further teaches generating antigen specific CTL and antibodies using xenogenic PAP in the case study with rats where it stimulates autoimmune prostatitis (p.10 col.2 paragraphs 0087-0091). Regarding claim 21, it is inherent that a probe can be generated from the nucleic acid sequences of said vaccine construct for hybridizing or detecting said construct. Thus the cited reference clearly teaches the invention as instantly claimed.

Response to Applicants' Arguments of *01/20/2010:*

The Applicant argues that Mcneel reference only teaches using plasmid vector containing PAP antigen coding sequences and does not teach PAP antigen vaccine in viral vectors especially avipox viral vectors and hence is not appropriate as 102 (e) reference.

Applicants, arguments are however, found not persuasive because although main focus in Mcneel reference is using of plasmid as a PAP vaccine vector it clearly teaches a vaccine construct comprising a vaccinia virus vector (which is a pox virus vector) and encoding and expressing a xenogenic prostrate specific polypeptide (paragraphs 0087-0091), Further McNeel teaches established art of using booster virus vector containing same target antigen encoding sequences (here specifically teaches using a fowl pox virus vector e.g., see paragraph 0046). Thus MCNeel reference establishes a prior art

knowledge of using vaccines for PAP in fowl pox vector (avipox virus) construct as well as using xeno antigens. Hence the rejection is appropriate and is here by maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 11-19 and 21 stand rejected under 35 USC 103 (a) as being unpatentable over McNeel et al., (US200401428290 A1; art of record) in view of Schlom et al., (WO 01/95919; art of record).

The above claims are drawn to a genetic vaccine construct comprising an avipox virus vector that encodes and expresses in a subject a xenogenic prostate specific polypeptide or a derivative thereof, without productively infecting said subject and further drawn to a said genetic vaccine construct additionally comprising a sequence of nucleotides encoding an immunostimulatory polypeptide and still further drawn a hybridization probe for detecting said constructs.

Regarding claims 1, 3-6, 11-17, 19 and 21 McNeel teaches vaccine construct comprising a poxvirus vector and encoding and expressing a xenogenic prostrate specific polypeptide, specifically prostatic acid phosphatase (human), and administering to a rat (see entire article; abstract; p.10 col.2 paragraphs 0087-0091). McNeel further teaches using fowlpox virus vector expressing the same antigenic polypeptide (PAP) as a “boost” in the prime boost protocols (p.6, paragraph 0046). Fowl poxvirus is amply known in the prior art (inherent in the prior art) for not exhibiting pathogenic replication indicating it does not productively infect the targeted mammalian subject. McNeel further teaches generating antigen specific CTL and antibodies using xenogenic PAP in the case study with rats where it stimulates autoimmune prostatitis (p.10 col.2 paragraphs 0087-0091). Regarding claim 21, it is inherent that a probe can be generated from the nucleic acid sequences of said vaccine construct for hybridizing or detecting said construct. McNeel however, does not teach co-expressing a cytokine gene in the avipox construct.

Regarding the limitation of the co-expression of a cytokine gene with a gene for prostrate specific antigen in an avipox virus vector in claims Schlom teaches a vaccine construct comprising an avipox virus (e.g., Fowl-pox virus) vector and encoding and expressing a prostrate specific polypeptide for e.g., PSA and/or in combination with a cytokine gene for e.g., GM-CSF (see entire article; abstract; p.10, lines 11-17, p.11, 5-17, p.12, lines 1-8, p.13, lines 6-25). Schlom further teaches that the fowl-pox virus vector does not exhibit pathogenic replication indicating it does not productively infect the mammalian subject (entire article; p.11, lines 5-14).

Thus it would have been obvious for one of ordinary skill in the art to incorporate in the vaccine construct of McNeel that expresses a xenogenic prostrate specific antigen, an immune enhancing cytokine gene and use it as an efficient vaccine for treating a prostrate tumor in a subject. One of ordinary skill in the art would have bee motivated to make and use vaccine construct with dual expression of a targeted antigen and a immunomodulatory cytokine as it would enhance the potency of the vaccine. One of ordinary skill in the art would have reasonable expectation of success making using vaccine construct expressing a xenogenic prostrate specific antigen and a cytokine gene because the art teaches that it is routine to use a xenogenic antigen to avoid immune tolerance observed with autoantigens and further art teaches that it is routine to use vaccine constructs that co-expressi certain immunomdoulatroy cytokines that effectively act as adjuvants, enhancing the immune response. Thus, the claimed invention was *prima facie*

Response to Applicants' Arguments of *01/20/2010:*

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Applicants, arguments are however, found not persuasive because although main focus in Mcneel reference is using of plasmid as a PAP vaccine vector it clearly teaches a vaccine construct comprising a vaccinia virus vector (which is a pox virus vector) and encoding and expressing a xenogenic prostrate specific polypeptide (paragraphs 0087-0091), Further McNeel teaches established art of using booster virus vector containing

same target antigen encoding sequences (here specifically teaches using a fowl pox virus vector e.g., see paragraph 0046). Thus MCNeel reference establishes a prior art knowledge of using vaccines for PAP in fowl pox vector (avipox virus) construct as well as using xeno antigens. Hence the rejection is appropriate and is here by maintained.

Conclusion:

No claim allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the

problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/
Primary Examiner, Art Unit 1633